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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,500	04/02/2004	Frank Jao	ARC 2258 C1	3152

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,500	JAO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement and Applicant's Arguments/Remarks, all filed 12/30/06 is acknowledged.

Applicant's election with traverse of Group I (claims 1-10) in the reply filed on 12/30/06 is acknowledged. The traversal is on the ground(s) that "a search for the novelty of a dosage form for delivering an antiepileptic drug encompassed by Group I would yield information regarding novelty of the process of maintaining the integrity and performance of a dosage form having a semipermeable wall enclosing an antiepileptic drug formulation encompassed by Group II. Therefore, Groups I and II together would not be a serious burden on the examiner." This is not found persuasive because as stated in the restriction requirement filed 12/18/06, the product can be made by a materially different process such as coating one material on the other. Moreover, the inventions are distinct, each from the other, as evidenced by the different classes and subclasses. The different inventions would entail different issues with regards to patentability and enablement and would require different searches in both patent- and non-patent databases and there is no expectation that the searches would be coextensive in scope. This creates an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim 11 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/30/06.

Claims 1-11 are pending in this action. Claim 11 has been withdrawn. Claims 1-10 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the semipermeable *material*" in claim 5, line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes *et al.* (U.S. Patent No. 4,058,122).

The instant invention is drawn to a dosage form for delivering an antiepileptic drug to a gastrointestinal tract, comprising: a compartment containing a drug formulation layer, the drug formulation layer comprising an antiepileptic drug; a semipermeable wall surrounding the compartment, the semipermeable wall having a passageway that allows communication between the compartment and an exterior of the dosage form; an internal lamina formed on an inner surface of the semipermeable wall, the internal lamina

being substantially soluble in water; wherein the internal lamina in a hydrated state forms a gelatinous layer that lubricates the semipermeable wall, thereby substantially preventing crack formation in the semipermeable wall while the dosage form is dispensing the drug.

Theeuwes *et al.* ('122) teach an osmotic system for delivering an agent. The system comprises a wall surrounding a compartment and has a passageway for delivering agent from the compartment. The wall is formed of laminae comprising a lamina consisting of a multiplicity of materials in laminar arrangement with a lamina consisting of a material or of a multiplicity of materials to provide a laminated wall that is permeable to agents and maintains its integrity during delivery of the agent. The compartment contains an agent that is soluble in an external fluid and exhibits an osmotic pressure gradient across the wall against the fluid or the agent has limited solubility in the fluid and is mixed with an osmotically effective compound soluble in the fluid and exhibits an osmotic pressure gradient across the wall against the fluid. Agent is released from the system by fluid being imbibed through the wall into the compartment at a rate controlled by the permeability of the wall and the osmotic pressure gradient across the wall producing a solution-containing agent or a solution of compound-containing agent (see Abstract). The laminated wall is formed of at least one semipermeable lamina; (col. 1, line 14 - col. 3, line 10).

The drawings demonstrate various osmotic systems of the invention. Figs. 1A and 1B, for instance, demonstrate an osmotic system 10 in the form of an oral, osmotic therapeutic system that is comprised of a body 11 having a semipermeable laminated wall 12 that surrounds a compartment 1, seen in Fig. 1B in opened section with a portion of wall 12 removed at 14. System 10 has a passageway 15 in wall 12 that extends through 12 and communicates with

compartment 13 and the exterior of system 10. Compartment 13 is a means for containing a beneficial agent 16 that is soluble in an external fluid and exhibits an osmotic pressure gradient across wall 12 against an external fluid or compartment 13 optionally contains a mixture of agents 16 with at least one agent exhibiting an osmotic pressure gradient (col. 3, line 54 – col. 4, line 14).

In Fig. 1C, wall 12 comprises a lamina consisting of an exterior semipermeable lamina 19 and an interior semipermeable lamina 20.

In one embodiment, lamina 19 is a composite comprising at least two materials blended to form a lamina that is (a) permeable to the passage of an external fluid, (b) maintains its physical and chemical integrity in the environment of use, and is more particularly substantially non-erodible and inert in the environment, c) provides mechanical support for other laminae comprising wall 12 and d) optionally is impermeable to compounds present in the environment of use (col. 4, lines 15-31).

In one embodiment, lamina 20 is a composite comprising at least two materials blended to form a semipermeable lamina that is (e) permeable to the passage of an external fluid, (f) substantially impermeable to passage of the agent and compound present in the compartment, (g) maintains its physical and chemical integrity in the presence of agent and is more particularly substantially non-erodible and inert in the presence of agent, h) provides mechanical support for other laminae forming wall 12 and i) is substantially impermeable to compounds present in the environment of use (col. 4, lines 32-61).

Materials suitable for forming laminae consisting of a single material are generically polymeric materials. The polymeric materials are homopolymers and copolymers and they

include materials known as semipermeable, osmosis and reverse osmosis materials (col. 7, line 22 – col. 8, line 6).

Representative materials of the wall include polymeric cellulose esters and copolymeric cellulose esters such as cellulose acylate, cellulose diacylate and cellulose triacylate (mono, di and tricellulose acylates) (col. 8, lines 7-10).

The semipermeable laminae forming materials also include cellulose ethers such as alkylcellulose, methylcellulose, ethylcellulose, ethylmethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose and the like (col. 10, lines 4-19).

Other semipermeable materials useful for forming laminae include copolymers of alkylene oxides and alkyl glycidyl ethers (col. 10, lines 20-47).

Active drugs for use in the invention include drugs that act on the central nervous system such as hypnotics and sedatives, including pentobarbital sodium, phenobarbital, secobarbital, thiopental and mixtures thereof (col. 20, lines 7-12).

It is noted that while Theeuwes does not explicitly teach the instantly claimed percentage of water-soluble polymers (of at least 80% by weight), generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, Applicants have not demonstrated any superior or unexpected results, which accrue from the claimed weight amount of water soluble polymer. The prior art recognizes and teaches a structurally similar dosage formulation comprising similar ingredients, used for the same field

of endeavor as that of the Applicants. No patentable distinction has been observed, which accrues from the instant amounts claimed since effective results are obtained using the dosage systems of Theeuwes.

Given the teachings of Theeuwes discussed above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Pertinent Art

Prior Art made of record, not relied upon and cited of interest:

- **Edgren *et al.*** (U.S. Pat. No. 5,190,763) (03/1993):

  Edgren *et al.* teach an osmotic dosage device comprising a wall (12) that surrounds and defines an internal compartment (15). The wall (12) comprises at least one exit means (13) that connects compartment (15) with the exterior of dosage form (10). Dosage form (10) can comprise more than one exit means. Representative materials for the semipermable wall include cellulose acylate, cellulose diacylate, cellulose triacylate (see col. 3, line 42 – col. 4, line 17).

- **Khan *et al.*** (U.S. Pat. No. 5,656,296) (08/1997):

  Khan *et al.* teach dual control sustained release drug delivery systems and methods for preparing, whereby the system comprises a core and a porous coating layer over the core (Abstract). Suitable drugs taught include antiepileptics, such as sodium phenytoin (col. 3, line 44).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N. SHEIKH
PRIMARY EXAMINER
TC-1600

Art Unit 1615

February 16, 2007

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